

Vanda Pharmaceuticals Inc.
Form 8-K
October 14, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 13, 2015

VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-34186
(Commission File No.)

03-0491827
(IRS Employer Identification No.)

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2200 Pennsylvania Avenue NW

Suite 300E

Washington, DC 20037

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (202) 734-3400

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- .. Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- .. Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- .. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- .. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On October 13, 2015, Vanda Pharmaceuticals Inc. (the Company) filed four separate patent infringement lawsuits in the United States District Court for the District of Delaware asserting U.S. Patent No. 9,138,432 (the 432 Patent), recently listed on the U.S. Food and Drug Administration (the FDA) publication Approved Drug Products With Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Two of these lawsuits join existing litigations against the Fanapt Abbreviated New Drug Application (ANDA) filers, Roxane Laboratories, Inc. (Roxane) and Inventia Healthcare Pvt. Ltd. (Inventia). The other two lawsuits are filed against new ANDA filers, Taro Pharmaceuticals, U.S.A., Inc./Taro Pharmaceuticals Industries Ltd. (Taro) and Apotex Inc. (Apotex), in which the Company is additionally asserting the Company's U.S. Patent No. 8,586,610 (the 610 Patent).

The first of these lawsuits, which was filed against Roxane, seeks an adjudication that Roxane has infringed the 432 Patent by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the 432 Patent in September 2025. This lawsuit is separate from the Company's two pending cases against Roxane relating to the 610 Patent and Aventisub LLC's U.S. Patent No. RE39,198, which are scheduled to be tried together in a four-day bench trial beginning on February 29, 2016.

The second of these lawsuits, which was filed against Inventia, seeks an adjudication that Inventia has infringed the 432 Patent by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the 432 Patent in September 2025. This lawsuit is separate from the Company's pending case against Inventia relating to the 610 Patent, which is scheduled to be tried in a four-day bench trial beginning on January 17, 2017.

The third of these lawsuits, which was filed against Taro, seeks an adjudication that Taro has infringed one or more claims of the 432 Patent and the 610 Patent by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the 432 Patent in September 2025 and the 610 Patent in November 2027.

The fourth of these lawsuits, which was filed against Apotex and Apotex Corp., seeks an adjudication that Apotex has infringed one or more claims of the 432 Patent and the 610 Patent by submitting to the FDA an ANDA for a generic version of Fanapt® prior to the expiration of the 432 Patent in September 2025 and the 610 Patent in November 2027.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VANDA PHARMACEUTICALS INC.

Dated: October 13, 2015

By: /s/ James P. Kelly

Name: James P. Kelly

Title: Senior Vice President, Chief Financial

Officer, and Treasurer